REMARKS/ARGUMENTS

Claims 1-3, 5-12, and 14-20 are pending in the application. Claims 1, 2, 8, 9, 11, and 12 have been amended. Support for the amendments can be found in the specification, for example, on pages 5 and 7, as well as in the original claims. No new matter has been added by way of amendment. Re-examination and reconsideration of the claims as amended are requested. Also, **Applicants respectfully request that the remarks and arguments presented herein be considered in accordance with MPEP §707.07(f)**, as the previously issued Final Office Action of April 8, 2004 and the Advisory Action of July 6, 2004, appear not to have taken into consideration Applicants' previously-made arguments.

In accordance with the Notice of Draftsperson's Patent Drawing Review dated March 3, 2000, and forwarded to Applicants with the Advisory Action of July 6, 2004, Applicants herewith submit formal drawings in accordance with the comments in the Notice. If these drawings are not acceptable, Applicants request clarification as to why the drawings are deemed not acceptable so that appropriate action can be taken to correct any problems.

The Objection to the Specification Should Be Withdrawn

Applicants note that the specification had been amended in Applicants' response of August 14, 2003 as suggested in the Office Action of June 17, 2003. However, the Office Action of April 8, 2004 reiterated the objection to the specification verbatim from the previously-issued Office Action (of June 17, 2003). Applicants were confused by this duplicate objection and again resubmitted these amendments with the Amendment After Final of June 7, 2004, but it seems that these amendments still have not been entered in the case. Accordingly, Applicants are again submitting these amendments herewith for the third time. If the objection to the specification is now made on a different basis, clarification is requested so that Applicants can properly address the objection.

The Rejection of Claims Under 35 U.S.C.§112, First Paragraph, Should Be Withdrawn

The Final Office Action dated April 8, 2004 (pages 2-3) rejected claims 1-3, 5-12, and 14-20 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description and enablement requirements. Applicants respectfully traverse these rejections.

Particularly, the Final Office Action (page 2) stated that a limitation that had been added to independent claims 1 and 8 constituted new matter and therefore the claims failed to comply with the written description requirement. This limitation recited that the engineered protein comprised an amino acid sequence which differed from the amino acid sequence of a native protein by at least one essential amino acid residue. While the specification does not provide *in haec verba* support for this limitation, Applicants believe that the description of the invention in the specification encompasses such embodiments. For example, on page 5 (lines 1-5) generally discuss the types of modifications that can be made to a protein, and on page 14 (lines 16-17), the specification discusses that "theoretically each variant contains zero to twenty-two additional methionines." Applicants note that "[i]n order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). Nevertheless, in order to advance prosecution, this limitation has been removed from the claims. Accordingly, the written description rejection on this basis should be withdrawn.

The Final Office Action (pp. 3-4) has maintained the rejection of claims 1-3, 5-12, and 14-20 as failing to comply with the written description requirement. The Office Action states that:

> Applicant does not describe a representative number of exemplary nucleic acid molecules that define the genus of sequence[s] having increased essential amino acid content as broadly claimed. There is *[sic*—are] insufficient relevant identifying characteristics to allow one of skiil *[sic*—skill] in the art to predictably determine the structure of other nucleic acid molecules absent further guidance.

Applicants respectfully disagree with this conclusion. The present specification discloses the amino acid sequences of VSPα and VSPβ, the sequences of several methionine-enriched VSPβ variants, and a nucleic acid molecule encoding an engineered protein (VSPβ-Met 10; see Figure 4). As previously acknowledged in the Office Action of June 17, 2003 (page 4):

> Applicant teaches proposed methionine enriched VSPβ variants based on conserved amino acid residues within VSP homologues (pages 15-16 and Figure 2); positions of possible tolerated amino acid substitutions within VSPβ (pages 16-19); a strategy for isolating correctly folded methionine enriched variants of VSPβ by testing for binding to a VSPβ specific antibody (pages 19-22) and methionine enriched variant VSPβ-[Met]10 binding to wild type VSPβ specific antibodies (page 19).

Thus, the present specification provides exemplary nucleotide and amino acid sequences as well as guidance regarding evaluation of the functional limitations of the claims.

Amended independent claim 1 and its dependent claims recite that the nucleic acid molecule comprises a nucleotide sequence which encodes an engineered VSPα or VSPβ protein comprising an amino acid sequence which differs from the amino acid sequence of a native protein, wherein said engineered protein has an altered amino acid composition in comparison to said native protein, wherein said altered amino acid composition comprises an increase in essential amino acid content to at least 5% and wherein said engineered protein binds to at least one antibody, monoclonal antibody, antibody fragment, or protein which binds to said native protein, wherein said native protein is VSPα or VSPβ.

Amended independent claim 8 and its dependent claims recite that the stably transformed plant has inserted into its genome a nucleotide sequence which encodes an engineered VSPα or VSPβ protein comprising an amino acid sequence which differs from the amino acid sequence of a native protein, wherein said engineered protein has an altered amino acid composition in comparison to said native protein, wherein said altered amino acid composition comprises an increase in essential amino acid content to at least 5% and wherein said engineered protein binds to at least one antibody, monoclonal antibody, antibody fragment, or protein which binds to said native protein, wherein said native protein is VSPα or VSPβ.

The Final Office Action (April 8, 2004, page 3) concluded that there are insufficient relevant identifying characteristics to allow one of skill in the art to predictably determine the

structure of other nucleic acid molecules absent further guidance. Applicants respectfully disagree. Applicants note that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *See,* Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, First Paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. 66 Fed. Reg. 1099, 1106 (2001). Applicants respectfully emphasize that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention.

Furthermore, the description of a claimed genus can be by structure, formula, chemical name, or physical properties. *See, Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I. 1992), citing *Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A genus of nucleotide sequences such as those recited in independent claims 1 and 8 may therefore be described by means of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *See, Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997); *see also* 66 Fed. Reg. 1099, 1106 (2001). The recitations that the native protein is VSPα or VSPβ and that the engineered VSPα or VSPβ protein binds to at least one antibody, monoclonal antibody, antibody fragment, or protein which binds to said native protein is sufficient to satisfy the written description requirement.

Consequently, contrary to the conclusion stated in the Office Action, the nucleotide sequences encompassed by genus claims 1 and 8 are defined by relevant identifying physical and chemical properties. In fact, the common attributes or features of the elements possessed by the members of these genera is that they encode an engineered VSPα or VSPβ protein which comprises an amino acid sequence that is defined in reference to VSPα or VSPβ. The necessary common features of the claimed genus are clear.

Applicants further note that the Federal Circuit has explicitly stated that

> *Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.

Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332 (Fed. Cir. 2003). *See also, Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320 (noting that "[i]n more recent cases, however, this court has distinguished *Lilly*" and further noting that in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956 (Fed. Cir. 2002), "neither the specification nor the deposited biological material recited the precise 'structure, formula, chemical name, or physical properties' required by *Lilly*.")

In summary, the description of a representative number of species *does not* require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Applicants submit that the relevant identifying physical and chemical properties of the disclosed genus would be clearly recognized by one of skill in the art and consequently, Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus. Accordingly, the rejection of claims 1-3, 5-12, and 14-20 under 35 U.S.C. §112, first paragraph, for lack of written description should be withdrawn.

The Final Office Action (April 8, 2004, page 3) maintained the rejection of claims 1-3, 5-12, and 14-20 as failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

The present specification discloses the amino acid sequences of VSPα and VSPβ, the sequences of several methionine-enriched VSPβ variants, and a nucleic acid molecule encoding an engineered protein (VSPβ-Met 10; see Figure 4). As noted in the previous Office Action (6/17/03, page 4):

> Applicant teaches proposed methionine enriched VSPβ variants based on conserved amino acid residues within VSP homologues (pages 15-16 and Figure 2); positions of possible tolerated amino acid substitutions within VSPβ (pages 16-19); a strategy for isolating correctly folded methionine enriched variants of VSPβ by testing for binding to a VSPβ specific

> antibody (pages 19-22) and methionine enriched variant VSPβ-[Met]10 binding to wild type VSPβ specific antibodies (page 19).

Thus, the present specification provides exemplary nucleotide and amino acid sequences as well as guidance regarding evaluation of the functional limitations of the claims. Applicants believe that the teachings of the present specification, when considered by those of skill in the art, satisfy the enablement requirement.

The Final Office Action (page 4) made a number of statements regarding the enablement rejection, as follows; statements are numbered for ease of reference in the comments that follow. The Office Action stated that:

> **[1]** Applicant teaches methionine enriched variant VSPβ-[Met]10 binding to wild type VSPβ specific antibodies (page 19) which only suggest that VSPβ-[M]et10 may be correctly folded in an E. coli secretion system as stated by Applicant in the specification on page 20, lines 1-2. This does not meet [the] required level of certainty as recited in the limitation of Claims 1 and 8 "retains the conformation of the native protein and therefore binds." **[2]** Further, Applicant has not addressed the Examiner's statements in the enablement rejection directed towards the limitations of monoclonal antibodies in discriminating against non-native or non-corresponding VSPβ variants. **[3]** Moreover, the results Applicant recites on page 19 of the specification do not indicate any background binding as relative control. **[4]** Furthermore, no guidance is provided for making an engineered protein having an altered amino acid composition that would bind to a modified protein that binds to a native protein. It is uncertain which alteration would be compatible with the other alterations and how one would assay for productive binding. **[5]** Nonetheless, undue experimentation would be required to make, clone, and express a multitude of non-exemplified variants of a nucleic acid molecule encoding a protein engineered for an increase in the level of essential amino acids, that binds with an antibody or protein molecule that also binds with a native form of the engineered protein and would require one of skill in the art to test in a myriad of non-exemplified plants for expression.

These statements, considered collectively, indicate that the Examiner is applying an inappropriately high standard of enablement to the present claims. Applicants respectfully submit that the present claims meet the enablement requirement and should be allowed.

With regard to statement 1, claims 1 and 8 have been amended to remove the limitation requiring that the engineered protein retains the conformation of the native protein. It is

expected that the engineered VSPα or VSPβ proteins of the claims will retain the conformation of the native VSPα or VSPβ protein as determined by their ability to bind to at least one antibody, monoclonal antibody, antibody fragment, or protein. Indeed, the Office Action acknowledged that the working example provided on page 19 of the specification, which teaches that the exemplary engineered protein VSPβ-Met10 binds to wild type VSPβ antibodies, suggests that VSPβ-Met10 is correctly folded in an *E. coli* secretion system. Nevertheless, in order to advance prosecution, the claims have been amended. Therefore, the rejection of claims on the basis that this limitation imposed a requirement for additional information has been obviated.

With regard to statement 2, the Final Office Action was apparently referring to the comments in the previous Office Action of June 17, 2003 (page 5, first paragraph), which stated that:

> Interacting molecules do not predictably interact with proteins. Bendayan S. *et al.* teach a Mab raised against one antigen cross-reacting with determinants from other proteins [citation omitted]. Further, it is well known in the art that Mab recognize linear portions of a protein of up to 8 contiguous amino acids and thus, would not necessarily discriminate against non-native or non-corresponding VSPβ variants.

Those of skill in the art are aware of such phenomena and would be able to make and test antibodies for particular experiments that suited the needs of those experiments. One of skill in the art would also be able to make and use a panel of antibodies that distinguished between native proteins and proteins that had a different conformation than the native protein if the situation required such an evaluation. However, these are not requirements of the claims. The Examiner appears to be reading additional limitations into the claims and then rejecting those "phantom claims" for lack of enablement, which is not the appropriate analysis. The present claims meet the enablement requirement and should be allowed.

Similarly, the Office Action in statement 3 indicates that the Examiner wishes that rather than simply describing the results of the experiments provided in the working examples, Applicants had provided detailed raw data from those experiments. Applicants are unaware of any requirement that raw data be provided in an application. Moreover, those of skill in the art are accustomed to descriptions of experiments that summarize the results, *e.g.*, at scientific meetings, and, without more, would not have reason to doubt results reported in this manner. If

the Examiner has reason to doubt Applicants' description of the experiments in the specification as filed, he is invited to provide an affidavit under 37 C.F.R. §104(d)(2) explaining the basis therefor so that Applicants may understand and properly address the rejection.

With regard to statement 4, Applicants note that independent claims 1 and 8 (and therefore the remaining claims, which are dependent thereon) have been amended to remove the objected-to term, "modified protein." This term is defined in the specification, but the term "protein" which remains in the claims encompasses all types of proteins, whether modified or unmodified. Accordingly, the rejection on this basis, if any, should be removed. In this context, Applicants note the working example described on page 21, which teaches a filter lift assay involving the binding of a native protein to various engineered VSPβs:

> Fifty *E. coli* colonies containing randomly mutated VSPβ genes were picked as small patches to an SB agar plate containing glucose and ampicillin. Patches were allowed to grow overnight at 37°C and were then transferred to a nitrocellulose filter. On the surface of an SB agar plate containing ampicillin and IPTG, this filter was placed on top (cell-side up) of a separate blocked filter to which the antigen (*e.g.*, VSPα) had been coated. During an overnight incubation at 30°C, the cells expressed the VSPβ variant they encoded. These proteins were able to diffuse through the top filter and, if correctly folded, bind the antigen-coated filter below. The next day, the antigen-coated filter was washed with PBS-0.05% Tween and incubated with HRP/anti-e tag conjugate. Since the VSPβ mutants are cloned into the pCANTAB-5E vector which fuses a C-terminal epitope tag (e-tag) to the VSPβ protein variants, bound proteins were detected by this antibody in combination with enhanced chemiluminescence detection.

Thus, working examples are provided in the specification illustrating the use of protein-protein interactions.

In statement 5, the Examiner concludes that undue experimentation would be required to "make, clone, and express a multitude of non-exemplified variants of a nucleic acid molecule encoding a protein engineered for an increase in the level of essential amino acids, that binds with an antibody or protein molecule that also binds with a native form of the engineered protein and would require one of skill in the art to test in a myriad of non-exemplified plants for expression." Applicants respectfully disagree with this conclusion.

First, in contrast to the conclusions stated in the Office Action, guidance is provided as to the limitations of the claims. Applicants have provided exemplary sequences of VSPα and VSPβ, as well as exemplary sequences of "VSPβ-Met10," "VSPβ-Met20," and "VSPβ-Met30" (see, *e.g.*, the sequence listing). Applicants have provided extensive guidance for making proteins having altered amino acid compositions, for example, on pages 5-7 (guidance for making substitutions and discussing changes in essential amino acid content) and in the Experimental section on pages 13 *et seq*. Particularly, pages 13 and 16-17 include an extensive discussion of various protein modification strategies and describe positions expected to tolerate conservative and non-conservative substitutions; see also the data provided in Tables 1 and 2 on pages 22 and 23. The specification also provides a working example (on p. 19) in which VSPβ-Met10 was produced in *E.coli* and found to bind to the same antibodies as wild-type VSPβ. This example also provides guidance for using antibodies to bind to a native or engineered protein, and further guidance is provided for protein-protein interactions in the working example described on page 14. Applicants believe that this amount of guidance is sufficient for one of skill in the art to make and use the claimed invention.

Applicants stress that when evaluating the quantity of experimentation required, the court looks to the amount of experimentation required to practice a single embodiment of the invention rather than the amount required to practice every embodiment of the invention. For example, in *Wands*, the claims at issue were drawn to immunoassay methods using any monoclonal antibody having a binding affinity for HbsAg of at least 10^{-9} M. The PTO had taken the position that the claim was not enabled, as it would take undue experimentation to make the monoclonal antibodies required for the assay. The Federal Circuit reversed and held that the claims were enabled because the amount of experimentation required to isolate monoclonal antibodies and screen for those having the correct affinity was not undue. *See Id.* Clearly, the Federal Circuit did not contemplate that every antibody useful in the methods of the claim must be identified. Rather, the court considered the amount of experimentation required to identify one or a few monoclonal antibodies having the required affinity. *See also, Johns Hopkins University v. Cellpro*, 931 F. Supp. 303, 324 (D. Del. 1996), *aff'd in part, vacated in part, and remanded*, 47

USPQ2d 1705 (Fed. Cir. 1998) (stating that "[t]he specification need only enable one mode of making the claimed invention.").

In the instant case, the quantity of experimentation required to practice the invention amounts to only a few steps: generating a nucleic acid molecule comprising a nucleotide sequence that encodes protein having an altered amino acid composition and determining whether that protein binds to at least one antibody or protein which binds to the corresponding native VSPα or VSPβ protein. All of these steps are readily within the skill of those in the art and such assays, while routine in the art, have further been presented in the specification, particularly in working examples described on pages 14 and 19. Some of the claims (*e.g.*, claim 8 and claims dependent thereon) are drawn to plants containing nucleotide sequences encoding such proteins, and the additional steps required to practice these claims are also routinely performed by those of skill in the art.

Ample guidance is therefore provided to allow one of skill in the art to make and use the claimed invention. Consequently, contrary to the conclusions stated in the Office Action, the quantity of experimentation necessary and the amount of guidance presented in the specification is sufficient to enable the claimed nucleic acid molecules and plants. Accordingly, the rejection of the claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been overcome. Accordingly, it is respectfully submitted that the rejections under 35 U.S.C. § 112, first paragraph, should be withdrawn.

The Rejection of Claims Under 35 U.S.C.§112, Second Paragraph, Should Be Withdrawn

The Final Office Action of April 8, 2004 (page 5) rejected claims 1-3, 5-12, and 14-20 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Claim 1 and other claims were rejected as being indefinite due to their recitation of "at least about"; the claims have been amended in order to clarify the lower limit of the claim.

Similarly, claims 1 and 8 were rejected as indefinite for their recitation of "capable of binding," and these claims have been amended as suggested to clarify that scope of the claims. Support for the amendments can be found throughout the specification, particularly for example on pages 2 and 7. Applicants note that one of skill in the art will appreciate that the claim does not require simultaneous binding by a particular antibody, monoclonal antibody, antibody fragment, or protein to both the native and engineered protein, as demonstrated, for instance, in the working example provided in the specification on page 21 ("Filter Lift Assay").

Claims 1 and 8 were also rejected as indefinite for reciting a broad range or limitation together with a narrow range or limitation. Applicants note that these claims have been amended for clarification to remove the narrower range or limitation; accordingly, this ground for rejection has been obviated by amendment.

In view of the above amendments and comments, Applicants respectfully submit that the rejection of claims under 35 U.S.C. §112, second paragraph, should be withdrawn.

The Rejection of Claims Under 35 U.S.C. §102(e) Should Be Withdrawn

The Final Office Action (page 5) and the Advisory Action of July 6, 2004, maintained the rejection of claims under 35 U.S.C. §102 as anticipated by references previously cited against the claims in this case. Applicants are confused by this rejection because, as discussed in Applicants' previous response of August 14, 2003 and the Amendment After Final filed June 7, 2004, **the cited references do not teach all of the limitations of the claims and therefore cannot anticipate the claims under 35 U.S.C. §102**. Indeed, the rejections in the Final Office Action and the Advisory Action appear to have been repeated almost verbatim from the previously issued Office Action of June 17, 2003, despite the amendments and arguments in Applicants' response of August 14, 2003 (retransmitted to the PTO on December 18, 2003), which were apparently not considered. **Applicants respectfully request that the remarks and arguments presented herein be considered in accordance with MPEP §707.07(f)**, as the previously issued Final Office Action of April 8, 2004 and the Advisory Action of July 6, 2004, appear not to have taken into consideration Applicants' previously-made arguments.

The Final Office Action (page 6) maintained the rejection of claims 1-3, 5-11, 14, and 17-18 under 35 U.S.C. §102(e) as being anticipated by Jung R. *et al.* Applicants again respectfully traverse this rejection. Independent claims 1 and 8 (and therefore claims 2-3 and 5-7 which are dependent on or incorporate the limitations of claim 1 and claims 9-12 and 14-20 which are dependent on or incorporate the limitations of claim 8) **were previously amended** (in Applicants' response of August 14, 2003) **to include additional limitations**. Particularly, independent claims 1 and 8 now include the limitation that the native protein is VSPα or VSPβ. **The Jung reference does not teach or suggest this limitation and therefore cannot anticipate the subject matter of the claims**. Accordingly, Applicants respectfully submit that the rejection of claims 1-3, 5-11, 14, and 17-18 under 35 U.S.C. §102(e) as being anticipated by Jung R. *et al.* should be withdrawn.

The Final Office Action and the Advisory Action maintained the rejection of claims 1-3, 5-12, 15-16, and 18-20 under 35 U.S.C. §102(e) as anticipated by Tarczynski *et al.* U.S. Pat. No. 6,080,913, filed September 25, 1996. Applicants respectfully traverse this rejection.

Independent claims 1 and 8 (and therefore claims 2-3 and 5-7 which are dependent on or incorporate the limitations of claim 1 and claims 9-12 and 14-20 which are dependent on or incorporate the limitations of claim 8) **were previously amended** (in Applicants' response of August 14, 2003) **to include additional limitations**. Particularly, independent claims 1 and 8 now include the limitation that the native protein is VSPα or VSPβ. **The Tarczynski reference does not teach or suggest this limitation and therefore cannot anticipate the subject matter of the claims**. Accordingly, Applicants respectfully submit that this rejection of the claims under 35 U.S.C. §102(e) should be withdrawn.

The Rejection of Claims Under 35 U.S.C. §103 Should Be Withdrawn

The Final Office Action (page 8) and the Advisory Action maintained the rejection of claims 1-3, 5-11, and 14-20 under 35 U.S.C. §103(a) over the Jung reference in view of Gordon-Kamm *et al.* (1990) *The Plant Cell* 2: 603-608. As in the Office Action of June 17, 2003, the

Final Office Action of 4/8/04 erroneously states that "[t]he claims are drawn to soybean and maize plants transformed with a nucleic acid molecule encoding a vegetative storage protein...."

Applicants again respectfully traverse this rejection. Applicants again note that **claims 1-4 are not drawn to transformed plants and therefore should apparently not have been included in this rejection**. In addition, the claims that are drawn to transformed plants are not limited to maize and soybean, as stated in the Office Actions. Applicants also reiterate that **the Jung reference has the same assignee as the present application and therefore the Jung reference is not available to be cited against the present application under 35 U.S.C. §103(c)**.

To emphasize this point, which was noted in Applicants' previously filed response of August 14, 2003 (retransmitted to the PTO on December 18, 2003), Applicants reiterate that **the assignee on the Jung reference (*i.e.*, Pioneer Hi-Bred International, Inc.) is the same assignee as the one on the present application**. Applicants provide herewith a copy of the assignment filed in the parent case, Application No. 08/988,015, which shows that these applications are assigned to Pioneer Hi-Bred International, Inc. Applicants here quote 35 U.S.C. 103(c) in its entirety, with the particularly pertinent text highlighted for the Examiner's convenience:

> Subject matter developed by another person, **which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102** of this title, **shall not preclude patentability** under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or **subject to an obligation of assignment to the same person**.

(35 U.S.C. §103(c)). Because the assignee of the Jung reference and the assignee of the present application are the "same person," **the Jung reference is not available as a reference against the present claims under 35 U.S.C. §103(c)**.

The only remaining reference cited against the claims is Gordon-Kamm *et al.* ((1990) *The Plant Cell* 2: 603-608). This reference is characterized in the Office Action as teaching "transformation of maize." Because the claims involve many more elements than the mere

transformation of maize, none of which are taught by Gordon-Kamm *et al.*, the claims are not rendered obvious in view of this reference.

Although the Tarczynski reference was not cited against the claims under 35 U.S.C. §103(c), Applicants again note that the assignee on the Tarczynski reference (*i.e.*, Pioneer Hi-Bred International, Inc.) is the same assignee as the one on the present application and therefore **the Tarczynski reference is not available as a reference against the present claims under 35 U.S.C. §103(c)**.

In view of the above arguments, Applicants respectfully submit that the rejection of claims under 35 U.S.C. §103(a) should be withdrawn.

Consideration Of Previously Submitted Information Disclosure Statement

Applicants **again** note (as they did in the previous response of August 14, 2003 which was retransmitted to the PTO per the Examiner's request on December 18, 2003, and the Amendment After Final of June 7, 2004) that an initialed copy of the PTO Form 1449 that was submitted with Applicants' Information Disclosure Statement filed January 6, 2000, has not been returned to Applicants' representative with the Office Action. In addition, an initialed copy of the PTO Form 1449 that was submitted with Applicants' Information Disclosure Statement filed August 14, 2003, has not been returned to Applicants' representative with the Office Action. Accordingly, it is **again** requested that an initialed copy of these Forms 1449 be forwarded to the undersigned with the next communication from the PTO. In order to facilitate review of the references by the Examiner, copies of the Information Disclosure Statements and the Forms 1449 are attached hereto. Copies of the cited references were provided at the time of filling the original Information Disclosure Statement, and, therefore, no additional copies of the references are submitted herewith. Applicants will be pleased to provide additional copies of the references upon the Examiner's request if it proves difficult to locate the original references.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the rejections of the claims under 35 U.S.C. §§112, 102, and 103 are overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

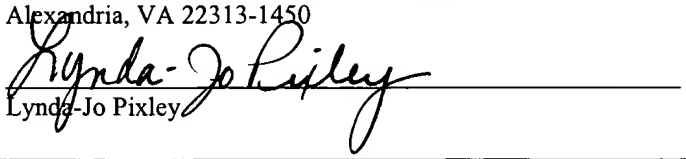
Respectfully submitted,

Leigh W. Thorne
Registration No. 47,992

Customer No. 29122
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Raleigh Office (919) 862-2200
Fax Raleigh Office (919) 862-2260

"Express Mail" mailing label number EL 387069268 US
Date of Deposit August 9, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to:
Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450



Lynda-Jo Pixley

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

JUNE 25, 1998

PTAS

100002171A

ALSTON & BIRD LLP
W. MURRAY SPRUILL
P.O. DRAWER 34009
CHARLOTTE, NC 28234

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 04/27/1998

REEL/FRAME: 9133/0920
NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
RAO, A. GURARAJ

DOC DATE: 04/07/1998

ASSIGNOR:
SLEISTER, HEIDI MAJOR

DOC DATE: 04/07/1998

ASSIGNEE:
PIONEER HI-BRED INTERNATIONAL, INC.
800 CAPITAL SQUARE
400 LUCUST STREET
DES MOINES, IOWA 50309

SERIAL NUMBER: 08988015
PATENT NUMBER:

FILING DATE: 12/10/1997
ISSUE DATE:

ANTIONE ROYALL, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

MRD 4-27-98

ASSIGNMENT

05-05-1998

100702171

R SHEET *Patents Only*

To the Honorable Commissioner of Patents a

April 22, 1998
Attorney Dkt:5718-16

Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

A. Guraraj Rao and Heidi Major Sleister

OTPE
APR 27 1998
PATENT & TRADEMARK OFFICE

Additional name(s) of conveying party(ies) attached? ___ Yes X No

2. Name and address of receiving party(ies):

Pioneer Hi-Bred International, Inc.
800 Capital Square
400 Locust Street
Des Moines, Iowa 50309

Additional name(s) & address(es) attached? ___ Yes X No

3. Nature of conveyance:

X Assignment
___ Merger
___ Security Agreement
___ Change of Name
___ Other _____

Execution Date: April 7, 1998

4. Application Serial No. 08/988,015 Patent No. _____

If this document is being filed together with a new application, the execution date of the application is: _____

Additional numbers attached? ___ Yes X No

5. Name and address of party to whom correspondence concerning document should be mailed:

W. Murray Spruill, Esq.
BELL SELTZER INTELLECTUAL PROPERTY LAW GROUP
ALSTON & BIRD LLP
P. O. Drawer 34009
Charlotte, NC 28234

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41) $ 40.00
X Enclosed
___ Authorized to be charged to deposit account

8. Deposit account number: 16-0605

DO NOT USE THIS SPACE

04/30/1998 BPAYNE 00000059 08988015
01 FC:581 40.00 OP

9. Statement and signature

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

W. Murray Spruill, Esq. Reg. No. 32,943
Name of Person Signing

WMSpr
Signature

4/22/98
Date

Total number of pages including cover sheet, attachments and document: 4

550403

Attorney Docket No 5718-16
CASE NO. 0379

ASSIGNMENT - WORLDWIDE

For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each undersigned inventor has sold and assigned, and by these presents hereby sells and assigns, unto

PIONEER HI-BRED INTERNATIONAL, INC.
800 Capital Square
400 Locust Street
Des Moines, Iowa 50309

its successors and assigns, the entire right, title and interest, so far as concerns the United States and the Territories and Possessions thereof and all foreign countries in and to the invention in **"COMPOSITIONS AND METHODS FOR ALTERING AMINO ACID CONTENT IN PROTEINS"**

as set forth in his United States Patent Application

☐ executed concurrently herewith
☒ executed on April 7, 1998
☒ Serial No. 08/988,015 filed December 10, 1997

said application for United States Letters Patent, including all divisional, renewal, substitute, continuation and Convention applications based in whole or in part upon said inventions or upon said applications, and any and all Letters Patent and reissues and extensions of Letters Patent granted for said inventions or upon said applications and every priority right that is or may be predicated upon or arise from said inventions, said applications, and said Letters Patent; said Assignee being hereby authorized to file patent applications in any or all countries on any or all said inventions in the name of the undersigned or in the name of said Assignee or otherwise as said Assignee may deem advisable, under the International Convention or otherwise; the Commissioner of Patents and Trademarks of the United States of America being hereby authorized to issue or transfer all said Letters Patent to said Assignee in accordance herewith; this assignment being under covenant, not only that full power to make the same is had by the undersigned, but also that such assigned right is not encumbered by any grant, license, or other right theretofore given, and that the undersigned will do all acts reasonably serving to ensure that the said inventions, patent applications and Letters Patent shall be held and enjoyed by said Assignee as fully and entirely as the same could have been held and enjoyed by the undersigned if this assignment had not been made, and particularly to execute and deliver to said Assignee all lawful documents including petitions, specifications, oaths, assignments, invention disclaimers, and lawful affidavits in form and substance which may be requested by said Assignee, to furnish said Assignee with all facts relating to said inventions or the history thereof and any and all documents, photographs, models, samples or other physical exhibits which may be of said inventions, and to testify in any proceedings relating to said inventions, patent applications, Letters Patent.

The undersigned hereby grant an authorized representative of Assignee the power to insert in this Assignment any further identification which may be necessary or desirable to comply with the rules of the U.S. Patent and Trademark Office for recordation of this Assignment.

IN WITNESS WHEREOF, I have hereunto set my hand and seal on this 7 day of April, 1998.

A. Gururaj Rao (SEAL)

A. Gururaj Rao

STATE OF IOWA)
) ss:
COUNTY OF Polk)

Before me personally appeared A. Gururaj Rao, to me known to be the person described in and who executed the foregoing instrument, and he acknowledged to me that he executed the same for the purpose therein stated, this 7 day of April, 1998.

Sharon Biller

Notary Public

SEAL

My Commission Expires: 7-19-98

IN WITNESS WHEREOF, I have hereunto set my hand and seal on this 7 day of April, 1998.

Heidi Major Sleister (SEAL)
Heidi Major Sleister

STATE OF IOWA)
) ss:
COUNTY OF Polk)

Before me personally appeared Heidi Major Sleister, to me known to be the person described in and who executed the foregoing instrument, and she acknowledged to me that she executed the same for the purpose therein stated, this 7 day of April, 1998.

Sharon Bills
Notary Public

SEAL

My Commission Expires: 7-19-98

COPY

Commissioner For Patents
Alexandria, VA 22313

Date Mailed: August 12, 2003
Atty. Dkt. No. 035718/193735

Application No. 09/478,567; Filing Date: January 6, 2000
Inventor(s): Rao *et al.*; Title of Invention: "COMPOSITIONS AND METHODS FOR ALTERING AMINO ACID CONTENT OF PROTEINS"
Documents Enclosed: IDS (1 page); Form 1449 (1 page); and Copies of 7 References

Check Enclosed: $0

Kindly acknowledge receipt by placing office stamp hereon and returning postcard to: **Lynda-Jo Pixley - ALSTON & BIRD LLP**

COPY

Assistant Commissioner For Patents
Washington, DC 20231

Date Mailed: 01/06/2000
Atty. Dkt. No. 5718-16B

Kindly acknowledge receipt of the accompanying DIVISIONAL PATENT APPLICATION with Application Transmittal Cover Sheet for:

Inventor(s): Rao et al.

Title of Invention: COMPOSITIONS AND METHODS FOR ALTERING AMINO ACID CONTENT OF PROTEINS

Pages of Spec. (including claims and abstract) 26; No. of Claims 20

No. of Drawing Sheets 8 ; Declaration Enclosed Yes - copy (4 pages)

Small Entity Statement Enclosed N/A;

IDS with PTO 1449 Enclosed yes-2 pages ; (No. of 1449 Cites Enclosed 1)

Assignment with Cover Sheet and $40.00 Fee Enclosed

Check(s) Enclosed $690.00

Please place office stamp hereon and Return Postcard to : WMS/ste

ALSTON & BIRD LLP